

**NOT FOR PUBLICATION**

**CLOSED**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

KING PHARMACEUTICALS, INC.,  
KING PHARMACEUTICALS RESEARCH  
AND DEVELOPMENT, INC., and WYETH

Plaintiffs,

V.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Civil Action No. 05-3855 (JAP)

## OPINION

PISANO, District Judge.

Plaintiffs King Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc. (together “King”) and involuntary Plaintiff Wyeth<sup>1</sup> (together “Plaintiffs”) brought this action for patent infringement against Defendant Teva Pharmaceuticals USA, Inc. (“Teva”). King alleges that Teva has infringed one or more claims of United States Patent No. 4,626,538 (“the 538 Patent”). This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Currently before the Court is (1) Plaintiffs’ Motion for Summary Judgment; (2) Teva’s Cross-Motion for Summary Judgment; and (3) Teva’s Motion to File First Supplemental and Amended Answer and Defenses (“Motion to Amend”). For the reasons expressed below, the Court grants Plaintiffs’ Motion for Summary Judgment and denies Defendant’s motions.

<sup>1</sup> King named Wyeth as an involuntary plaintiff to this action pursuant to Federal Rule of Civil Procedure 19.

## I. BACKGROUND<sup>2</sup>

This is an action for patent infringement of the 538 Patent,<sup>3</sup> under which King has the right, *inter alia*, to sell prescription zaleplon drug products in the United States. King sells Sonata®, a prescription zaleplon drug that is used to treat insomnia. The 538 Patent issued in 1986 subject to a terminal disclaimer that originally set the expiration date of the 538 Patent to coincide with the expiration date of United States Patent Nos. 4,654,347 (“the 347 Patent”) and 4,521,422 (“the 422 Patent”) and required common ownership of the three patents.<sup>4</sup> The 347 and 422 Patents expired on June 23, 2003. On June 4, 2003, however, the United States Patent and Trademark Office (“PTO”) extended the term of the 538 Patent for a period of 1810 days pursuant to 35 U.S.C. § 156. By operation of the § 156 Patent Term Extension (“PTE”), the 538 Patent will expire on June 6, 2008. The PTE did not apply to the 347 and 422 Patents, which do not cover Sonata®.

King commenced this action on August 2, 2005, after Teva filed Abbreviated New Drug Application (“ANDA”) No. 77-239 with the United States Food and Drug Administration (“FDA”) for approval to market generic versions of King’s Sonata® drug products. Plaintiffs allege that Teva’s ANDA filing constitutes patent infringement and that, if the FDA approves

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<sup>2</sup> For additional discussion of the facts, see *King Pharm., Inc. v. Teva Pharm. USA, Inc.*, No. 05-3855, 2006 WL 3933091 (D.N.J. Jan. 22, 2007) and *King Pharm., Inc. v. Teva Pharm. USA, Inc.*, 409 F. Supp. 2d 609 (D.N.J. 2006).

<sup>3</sup> The 538 Patent is entitled “[7-(3-Distributed Amino)PhenylPyrazolo[1,5-a]Pyrimidines.” (Compl. ¶ 9; Compl. Ex. A).

<sup>4</sup> The terminal disclaimer states: “Your petitioner . . . hereby disclaims the terminal part of any patent granted on the above-identified application . . . and hereby agrees that any patent so granted on the above-identified application shall be enforceable only for and during such period that legal title to said patent shall be the same as [the 347 and 422 Patents] . . . .”

Teva's ANDA, Teva will infringe the 538 Patent by, *inter alia*, manufacturing and selling zaleplon capsules in the United States. On September 22, 2005, Teva moved to dismiss the Complaint for failure to state a claim upon which relief can be granted, arguing that the 538 Patent expired on June 23, 2003 because, in Teva's view, the term of a terminally disclaimed patent may not be extended under 35 U.S.C. § 156. In a published opinion dated January 20, 2006, this Court denied Teva's motion, finding that neither § 156 nor any other provision of law renders "terminally disclaimed patents ineligible for a § 156 extension." *King Pharma, Inc.*, 409 F. Supp. 2d at 614, 615-18.<sup>5</sup>

On February 10, 2006, Teva filed an Answer setting forth the following eight affirmative defenses: (1) King's Complaint fails to state a claim upon which relief may be granted; (2) Teva's actions have not infringed—and will not infringe—the 538 Patent; (3) King's Complaint does not include facts showing that this is an exceptional case; (4) the 538 Patent has expired; (5) the PTE is invalid because it was improperly granted; (6) the 538 Patent is invalid for double patenting; (7) the 538 Patent is unenforceable due to violation of the common ownership requirement; and (8) the PTE of the 538 Patent renders it unenforceable.

Despite Teva's affirmative defense claiming that its actions do not and will not infringe the 538 Patent, the parties executed a Stipulation of Infringement on September 25, 2006. In substance, the Stipulation of Infringement is an admission on the part of Teva that if this Court found the 538 Patent to be valid and enforceable, then Teva's proposed manufacture and sale of zaleplon capsules would infringe the patent. (See Dkt. #52 (Stipulation of Infringement dated

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<sup>5</sup> The Federal Circuit has effectively affirmed that holding. See *Merck & Co. v. High-Tech Pharmacal Co.*, 482 F.3d 1317, 1324 (Fed. Cir. 2007) (holding that "a patent term extension under § 156 may be applied to a patent subject to a terminal disclaimer").

Sept. 25, 2006)). On October 24, 2006, Teva moved for summary judgment on the grounds that the 538 Patent was unenforceable due to violation of the terminal disclaimer's common ownership requirement.

The central issue of that motion was whether the Patent Assignment and the Asset Transfer Agreement—the documents controlling the transfer of rights in the 538 Patent from Wyeth to King—granted King an assignment of legal title and all substantial rights in the 538 Patent. Contrary to Teva's interpretation of the documents, the Court found, in an Opinion dated January 22, 2007 (the "January 22, 2007 Opinion"), that "the Patent Assignment and Asset Transfer Agreement constitute a *license* of the 538 Patent from Wyeth to King granting King rights related only to prescription zaleplon products." *King*, 2006 WL 3933091, at \*5 (emphasis added). The Court further found that there was no violation of the terminal disclaimer because Wyeth maintained common ownership of the 347, 422 and 538 Patents until the 347 and 422 Patents expired. *Id.* at \*3, 7. Based on those findings, the Court concluded that the 538 Patent "is valid and enforceable." *Id.* at \*7.

Plaintiffs now move for summary judgment, arguing that none of Teva's affirmative defenses pass muster in light of the Court's two prior decisions and the Stipulation of Infringement. In response, and in support of its Cross-Motion for Summary Judgment, Teva argues that issues of material fact remain regarding the validity of the 538 Patent. Teva also contends that King is estopped from claiming that it has a license in the 538 Patent because that representation contradicts statements that King has made to the PTO. Finally, in its Motion to Amend, Teva seeks leave to amend its Answer to include the affirmative defense of judicial estoppel, which Teva raised for the first time in its brief in opposition to Plaintiffs' Motion for

Summary Judgment.

## II. DISCUSSION

### *A. Teva's Motion to Amend and Cross-Motion for Summary Judgment*

As part of its opposition to Plaintiffs' Motion for Summary Judgment, Teva has filed a Cross-Motion for Summary Judgment claiming that it is entitled to judgment as a matter of law under the doctrine of judicial estoppel. Specifically, Teva argues that King is estopped from arguing to this Court that it has a license in the 538 Patent because King has previously represented to the PTO that it is the owner of the entire right, title and interest in a patent application—United States Patent Application No. 10/924,436 (“the 436 Application”)—which was conveyed to King via the Patent Assignment. In Teva's view, because the Patent Assignment, which incorporates the Asset Transfer Agreement and defines King's interest in the 538 Patent, “transfers identical rights to all three of the patent properties listed therein, it is inescapable that King considers itself also to be the owner of the entire right, title and interest in the 538 Patent.” (Teva's Opp. Br. at 12). In response, King contests Teva's judicial estoppel argument on the merits and argues that Teva waived this affirmative defense because it is absent from Teva's Answer. Not surprisingly, given the nature of this particular litigation, King's waiver argument prompted Teva to file its Motion to Amend.

Federal Rule of Civil Procedure 15(a) states, in relevant part, that “a party may amend the party's pleading only by leave of court or by written consent of the adverse party; and leave shall be freely given when justice so requires.” A district court has “substantial leeway in deciding whether to grant leave to amend,” but must provide a justification for the denial of a motion to amend. *Lake v. Arnold*, 232 F.3d 360, 373 (3d Cir. 2000). “Among the grounds that could

justify a denial of leave to amend are undue delay, bad faith, dilatory motive, prejudice, and futility.” *Krantz v. Prudential Invs. Fund Mgmt. LLC*, 305 F.3d 140, 144 (3d Cir. 2002).

It is undisputed that Teva was in possession of the information underlying its judicial estoppel argument no later than June 26, 2006, but waited until April 11, 2007 to file the instant Motion to Amend. In Teva’s view, that nine-month delay is insufficient to justify the denial of its Motion to Amend for undue delay. Contrary to Teva’s argument, however, the undue delay inquiry does not focus solely on the length of the moving party’s delay. Instead, in this Court’s view, the length of the delay is one factor to be considered along with the specific circumstances surrounding the moving party’s request, the moving party’s explanation, if any, for the delay, and the current stage of the litigation.

During the relevant nine-month period, Teva unsuccessfully moved for summary judgment without raising the judicial estoppel defense or attempting to amend its Answer, even though King’s primary argument in opposition to that motion is the same one that now gives rise to Teva’s claim of judicial estoppel. Even after receiving that unfavorable decision, Teva waited another three months before seeking leave to amend its Answer. Moreover, Teva filed the instant motion only after King filed its Motion for Summary Judgment and argued that Teva waived the judicial estoppel defense—a defense that Teva raised for the first time in its opposition brief to King’s dispositive motion. Furthermore, Teva offers no excuse for its delay in seeking leave to amend. In light of the foregoing, the Court finds that Teva’s Motion to Amend, filed at the eleventh hour despite prior opportunities to raise the judicial estoppel argument and amend its Answer, is untimely. *See Arthur v. Maersk, Inc.*, 434 F.3d 196, 204 (3d Cir. 2006) (“When a party fails to take advantage of previous opportunities to amend, without adequate explanation,

leave to amend is properly denied.”).<sup>6</sup>

The Court further finds that granting Teva’s motion would result in substantial prejudice to Plaintiffs. Indeed, granting Teva’s motion and its corresponding request for discovery would require Plaintiffs to supplement their Motion for Summary Judgment or file a new motion altogether. That would force Plaintiffs to incur additional costs and expend more time and effort to address a defense could have been—but inexplicably was not—raised at a much earlier juncture in the case. Thus, the Court denies Teva’s Motion to Amend on grounds of undue delay and undue prejudice. Because judicial estoppel was the sole basis for Teva’s Cross-Motion for Summary Judgment, the Court also denies that motion.

Having denied Teva’s motions, the Court need not address the merits of Teva’s judicial estoppel claim. The Court notes, however, that the judicial estoppel argument lacks merit because King has not made any irreconcilably inconsistent representations. Indeed, the documents Teva relies upon relate to the 436 Application, not the patent-in-suit and, in any

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<sup>6</sup> Contrary to Teva’s argument, *Arthur* does not stand for the proposition that a delay of eleven months between discovery of the information giving rise to a motion to amend and the actual filing of the motion is insufficient to constitute undue delay. Putting aside the fact that there is no bright line rule concerning the length of time required to justify a finding of undue delay, the Court notes that the reference in *Arthur* to an eleven-month delay encompasses the period of time between the filing of the original complaint and the motion to amend. *See Arthur*, 434 F.3d at 204. Using that measure in this case, Teva’s delay covers more than one year: Teva filed its Answer on February 10, 2006 and did not file its Motion to Amend until April 11, 2007. The Court agrees, however, that the proper measure of the delay in this case includes only the time in between Teva’s discovery of the information giving rise to its Motion to Amend and the actual filing thereof. As discussed above, using that measure, the delay in this case is nine months. Applying that measure to the facts in *Arthur* reveals that the delay there was less than four months. *See id.* at 205. As such, Teva’s analogy to the eleven-month period in *Arthur* is not only misleading, but it does nothing to bolster Teva’s argument that its delay in filing the Motion to Amend somehow falls below a legal threshold for undue delay.

event, King has withdrawn the documents from the PTO.<sup>7</sup>

***B. Plaintiffs' Motion for Summary Judgment***

As an initial matter, Teva has abandoned its second, fourth, fifth, sixth, and eighth affirmative defenses. For the reasons stated below, the Court finds that the remainder of Teva's affirmative defenses lack merit. Consequently, the Court grants Plaintiffs' Motion for Summary Judgment.

**1. Standard of Review under Federal Rule of Civil Procedure 56(c)**

Summary judgment is appropriate under Federal Rule of Civil Procedure 56(c) "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law." The substantive law identifies which facts are critical or "material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. The non-moving party must offer specific facts that establish a genuine issue of material fact, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986).

The Court must consider all facts and their logical inferences in the light most favorable

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<sup>7</sup> Teva attaches great importance to the fact that the PTO has taken no action on King's withdrawals. This point is largely moot, however, because Wyeth's patent counsel has filed a formal Power of Attorney assuming responsibility for further prosecution of the relevant patent. Moreover, the PTO's lack of action does not alter the Court's conclusion that King has not made inconsistent representations concerning the patent-in-suit.



to the non-moving party. *Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The Court shall not “weigh the evidence and determine the truth of the matter,” but need determine only whether a genuine issue necessitates a trial. *Anderson*, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a “mere scintilla” of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of N. Am.*, 974 F.2d 1358, 1363 (3d Cir. 1992).

## **2. Teva’s Third Affirmative Defense**

Plaintiffs argue that Teva’s third affirmative defense—that this is not an exceptional case—is not a defense to liability for patent infringement. In response, Teva contends that Plaintiffs have not carried their burden of establishing that they are entitled to summary judgment on this issue. In a sense, both parties are correct. Pursuant to 35 U.S.C. § 285, “[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party.” The exceptional case inquiry has no bearing whatsoever on the liability determination, and an affirmative defense challenging a plaintiff’s invocation of the exceptional case provision is insufficient to defeat a claim for patent infringement. Teva is correct, however, that Plaintiffs have not established that they are entitled to attorney fees as a matter of law. To the extent that Plaintiffs wish to pursue an award of attorney fees, the Court directs them to file the appropriate motion. The Court finds, however, that Plaintiffs are entitled to summary judgment on Teva’s third affirmative defense because it is not a proper defense to liability.

## **2. Teva’s First and Seventh Affirmative Defenses**

Teva’s first and seventh affirmative defenses rely upon the same allegation: the 538 Patent is invalid due to violation of the common ownership requirement of the terminal

disclaimer. In support of their Motion for Summary Judgment, Plaintiffs assert that the findings set forth in the January 22, 2007 Opinion, namely that there was no violation of the common ownership requirement and that the 538 Patent is valid and enforceable, dispose of Teva's argument and entitle Plaintiffs to summary judgement. The Court agrees.

In the January 22, 2007 Opinion, this Court analyzed the relevant portions of the Patent Assignment and Asset Transfer Agreement and concluded that Wyeth merely granted King a license in the 538 Patent, that the conveyance of that interest did not violate the common ownership requirement, and that the 538 Patent is thus valid and enforceable:

[H]aving analyzed the substance of the agreement between Wyeth and King, the Court finds that King [i]s a mere licensee of the 538 Patent. Thus, Wyeth continued to own the 347, 422, and 538 Patents after execution of the Patent Assignment and Asset Transfer Agreement. Because the Patent Assignment and Asset Transfer Agreement did not sever common ownership of the patents, there [i]s no violation of the terminal disclaimer. Therefore, the 538 Patent is valid and enforceable.

*King*, 2006 WL 3933091, at \*3.

Notwithstanding what the Court considers to be a clear explanation of its findings, Teva claims that the January 22, 2007 Opinion does not represent a conclusive finding that the Patent Assignment and Asset Transfer Agreement granted a license in the 538 Patent from Wyeth to King. Instead, Teva argues, the Court reached the above conclusion only because the applicable standard of review required the Court to view the facts in the light most favorable to King, the non-moving party. As such, the January 22, 2007 Opinion is merely a denial of summary judgment, not a binding legal conclusion that King has a license in the 538 Patent. Teva further argues that it has discovered previously unavailable evidence confirming that Wyeth, in fact, assigned the 538 Patent to King and that this evidence, at the very least, raises genuine issues of

material fact.

Although Teva correctly recites the standard of review for a summary judgment motion, it mis-characterizes the substance of the January 22, 2007 Opinion. The Court did not simply deny Teva's Motion for Summary Judgment on the grounds that there existed a genuine issue of material fact. Nor did the Court's determination that the Patent Assignment and Asset Transfer Agreement granted King a license in the 538 Patent turn on the applicable standard of review. To the contrary, the Court interpreted the Patent Assignment and Asset Transfer Agreement and made a threshold legal determination that, based on the meaning of those documents, King is a licensee of the 538 Patent. *See id.* at \*3-7.

Furthermore, the "newly available evidence" that Teva now presents to the Court does not alter the Court's earlier findings. Teva points to several documents, including corporate press releases, King's public filings with the Securities & Exchange Commission and Wyeth's 2003 Annual Report, that demonstrate, according to Teva, that the Patent Assignment and Asset Transfer Agreement constitute an assignment of the 538 Patent from Wyeth to King. Once again, however, this argument ignores the Court's previous finding that Patent Assignment and Asset Transfer Agreement unambiguously establish that King has a license in the 538 Patent. Under New York law, a party may not offer "extrinsic evidence . . . to shed light on the subjective intent of the parties to a contract if the contract is unambiguous on its face."<sup>8</sup> *Keene Corp. v. Bogan*, No. 88-0217, 1990 WL 1864, at \*6 (S.D.N.Y. Jan. 11, 1990); *W.W.W. Assocs., Inc. v. Giancontieri*, 77 N.Y.2d 157, 163 (N.Y. 1990) ("It is well settled that extrinsic and parol

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<sup>8</sup> Section 5.07 of the Asset Transfer Agreement provides that the Patent Assignment and Asset Transfer Agreement are to be construed under New York law.

evidence is not admissible to create an ambiguity in a written agreement which is complete and clear and unambiguous on its face.”). Having already determined that the Patent Assignment and Asset Transfer Agreement unambiguously convey to King a license in the 538 Patent, the Court rejects Teva’s invitation to sidestep the parol evidence rule and look beyond the four corners of those documents.<sup>9</sup>

Moreover, even if it were proper for the Court to consider extrinsic evidence tending to show that Wyeth and King previously characterized King’s interest in the 538 Patent as an assignment, it is doubtful that the evidence would have any impact on the Court’s conclusion. Indeed, as the Court explained in the January 22, 2007 Opinion, the nature of the interest conveyed does not depend upon the title that the parties attach to the conveyance. *See Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891) (“Whether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name by which it calls itself, but upon the legal effects of its provisions.”). Thus, notwithstanding what King and Wyeth might have represented to the public, it is the substance of that Patent Assignment and the Asset Transfer Agreement that controls here.

Thus, the Court reiterates its previously-stated conclusion: Wyeth owns the patent-in-suit and King is a licensee. The conveyance of that license does not violate the common ownership

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<sup>9</sup> The Court agrees with Teva that, as a general matter, “one must ascertain the intention of the parties and examine the substance of what was granted” when determining whether an agreement conveys an assignment or a license. *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 874 (Fed Cir. 1991). Here, however, *Vaupel* does not require the Court to look beyond the Patent Assignment and Asset Transfer Agreement for the same that the parol evidence rule applies: the express language of the Patent Assignment and Asset Transfer Agreement conclusively and unambiguously establishes that the interest transferred from Wyeth to King is a license.

requirement of the terminal disclaimer and the 538 Patent remains valid and enforceable.<sup>10</sup>

Because the Court holds, as it did in the January 22, 2007 Opinion, that the 538 Patent is valid and enforceable and Teva has conceded infringement via the parties' Stipulation of Infringement, there are no genuine issues of material fact with the respect to the merits of Plaintiffs' claim for patent infringement. Accordingly, the Court finds that Plaintiffs are entitled to judgment as a matter of law.

### **III. CONCLUSION**

For the reasons expressed above, the Court (1) grants Plaintiffs' Motion for Summary Judgment; (2) denies Teva's Cross-Motion for Summary Judgment; and (3) denies Teva's Motion to Amend. An appropriate order accompanies this opinion.

/s/ Joel A. Pisano  
JOEL A. PISANO, U.S.D.J.

Dated: August 3, 2007

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<sup>10</sup> The Court reaches the same conclusion with respect to Teva's argument that Wyeth transferred to King all substantial rights in the 538 Patent. In the January 22, 2007 Opinion, this Court found that the Patent Assignment and Asset Transfer Agreement "demonstrate that Wyeth did not transfer to King all substantial rights in the 538 Patent." None of Teva's new arguments compel the Court to alter its conclusion, which was made in reliance upon the express language of the controlling documents.